

## Claims

- 5 1. A method for the assessment of at least one quantity parameter and/or at least one quality parameter of biological particles in a liquid analyte material, comprising
- applying a volume of a liquid sample representing the analyte material, or particles isolated from a volume of liquid sample representing the analyte material, to an exposing domain from which exposing domain electromagnetic signals from the sample in the domain can pass to the exterior,
- 10 exposing, onto an array of active detection elements, an at least one-dimensional spatial representation of electromagnetic signals having passed from the domain, the representation being one which is detectable as an intensity by individual active detection elements, under conditions which will permit processing of the intensities detected by the array of detection elements during the exposure in such a manner that representations of electromagnetic signals from the biological particles are identified as distinct from representations of electromagnetic signals from background signals,
- 15 the size of the volume of the liquid sample being sufficiently large to permit the assessment of the at least one quantity parameter or the at least one quality parameter to fulfil a predetermined requirement to the statistical quality of the assessment based on substantially one exposure,
- 20 processing the intensities detected by the detection elements in such a manner that signals from the biological particles are identified as distinct from background signals,
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and correlating the results of the processing to the at least one quantity parameter and/or the at least one quality parameter of the liquid analyte material.

2. A method according to claim 1, wherein the exposing domain is a sample compartment having a wall part defining an exposing area, the wall part allowing electromagnetic signals from the sample in the compartment to pass through the wall and to be exposed to the exterior.

3. A method according to claim 2, wherein a volume of a liquid sample representing the analyte is arranged in the sample compartment.

4. A method according to any of the preceding claims, wherein the spatial representation of the electromagnetic signals is a two-dimensional image representation.

5. A method according to any of the preceding claims, wherein the array of detection elements is arranged in such a way that the a series of detection elements form a substantially straight line.

6. A method according to claim 5, wherein the array of detection elements is arranged in two directions in such a way that the detection elements form a series of substantially parallel straight lines, the series forming a rectangle.

7. A method according to any of the preceding claims, wherein the exposure of the spatial representation of electromagnetic signals onto the array of detection elements is performed by focusing an image of electromagnetic signals from at least a part of the exposing domain onto the array of detection elements by means of a focusing means.

8. A method according to claim 7, wherein the focusing means is a lens consisting of one or several elements.

9. A method according to any of the preceding claims, wherein the spatial representation exposed onto the array of detection elements is subject to such a linear

enlargement that the ratio of the image of a linear dimension on the array of detection elements to the original linear dimension in the exposing domain is smaller than 40:1.

10. A method according to claim 9, wherein the ratio is at the most 20:1

11. A method according to claim 10, wherein the ratio is smaller than 10:1.

12. A method according to claim 11, wherein the ratio is at the most 6:1.

13. A method according to claim 12, wherein the ratio is smaller than 4:1.

14. A method according to claim 9, wherein the particles the parameter or parameters of which is/are to be assessed are of a size of between  $1/3 \mu\text{m}$  to  $3 \mu\text{m}$ , and the ratio is in the range between 40:1 and 1:10.

15. A method according to claim 14, wherein the ratio is in the range between 20:1 and 1:10.

16. A method according to claim 15, wherein the ratio is in the range between 10:1 and 1:10.

17. A method according to claim 16, wherein the ratio is in the range between 6:1 and 2:1.

18. A method according to claim 9, wherein the particles the parameter or parameters of which is/are to be assessed are of a size between  $3 \mu\text{m}$  and  $100 \mu\text{m}$ , and the ratio is in the range between 3:1 and 1:100

19. A method according to claim 18, wherein the ratio is in the range between 2:1 and 1:100.

20. A method according to claim 19, wherein the ratio is in the range between 2:1 and 1:2.

21. A method according to claim 19, wherein the ratio is in the range between 1.4:1 and 1:100.

22. A method according to claim 21, wherein the ratio is in the range between 1:1 and 1:100.

23. A method according to any of the preceding claims, wherein the individual particles the parameter or parameters of which is/are to be assessed are imaged on at the most 25 detection elements.

24. A method according to claim 23, wherein the individual particles the parameter or parameters of which is/are to be assessed are imaged on at the most 16 detection elements.

25. A method according to claim 24, wherein the individual particles the parameter or parameters of which is/are to be assessed are imaged on at the most 9 detection elements.

26. A method according to claim 25, wherein the individual particles the parameter or parameters of which is/are to be assessed are imaged on at the most 5 detection elements.

27. A method according to any of the preceding claims, wherein the interior of the domain or sample compartment has an average thickness of between 20  $\mu\text{m}$  and 2000  $\mu\text{m}$ .

28. A method according to claim 27, wherein the interior of the domain or sample compartment has an average thickness of between 20  $\mu\text{m}$  and 1000  $\mu\text{m}$ .

29. A method according to claim 28, wherein the interior of the domain or sample compartment has an average thickness of between 20  $\mu\text{m}$  and 200  $\mu\text{m}$ .

30. A method according to any of the preceding claims, wherein the domain or sample compartment has dimensions, in a direction substantially parallel to the array of detection elements, in the range between 1 mm by 1 mm and 10 mm by 10 mm.

5 31. A method according to any of the preceding claims, wherein the volume of the liquid sample from which electromagnetic radiation is exposed onto the array is in the range between 0.01  $\mu$ l and 20  $\mu$ l.

10 32. A method according to claim 31, wherein the particles the parameter or parameters of which is/are to be assessed are of a size of between 1/3  $\mu$ m to 3  $\mu$ m, and the volume of the liquid sample from which electromagnetic radiation is exposed onto the array is in the range between 0.01  $\mu$ l and 1  $\mu$ l.

15 33. A method according to claim 31, wherein the particles the parameter or parameters of which is/are to be assessed are of a size of between 3  $\mu$ m to 100  $\mu$ m, and the volume of the liquid sample from which electromagnetic radiation is exposed onto the array is in the range between 0.04  $\mu$ l and 4  $\mu$ l.

20 34. A method according to any of the preceding claims, wherein the sample in the domain or sample compartment is at stand still during the exposure.

25 35. A method according to any of claims 1-33, wherein the sample in the domain or sample compartment is moved through the domain or sample compartment during the exposure, and wherein the exposure is performed over a sufficiently short period of time so substantially obtain stand still condition during the exposure.

30 36. A method according to any of the preceding claims, wherein at least a major part of the electromagnetic radiation emitted from the sample during exposure originates from or is caused by electromagnetic radiation supplied to the sample from a light source, at least a major part of the radiation from the light source having a direction which is transverse to the wall of the sample compartment or a plane defined by the domain.

37. A method according to any of the preceding claims, wherein the parameter to be assessed is the number of the biological particles per volume of the liquid analyte material.

5 38. A method according to any of claims 1-37, wherein the parameter(s) to be assessed is the size and/or shape of the biological particles in the liquid analyte material.

39. A method according to claim 37 or 38, wherein the size of the volume of the liquid sample is sufficiently large to allow identification therein of at least two of the  
10 biological particles.

40. A method according to claim 39, wherein the size of the volume of the liquid sample is sufficiently large to allow identification therein of at least four of the biological particles.

15 41. A method according to claim 40, wherein the size of the volume of the liquid sample is sufficiently large to allow identification therein of at least 10 of the biological particles.

20 42. A method according to claim 41, wherein the size of the volume of the liquid sample is sufficiently large to allow identification therein of at least 50 of the biological particles.

25 43. A method according to claim 42, wherein the size of the volume of the liquid sample is sufficiently large to allow identification therein of at least 100 of the biological particles.

30 44. A method according to claim 43, wherein the size of the volume of the liquid sample is sufficiently large to allow identification therein of at least 1000 of the biological particles.

45. A method for the assessment of at least one quantity parameter and/or at least one quality parameter of biological particles in a liquid analyte material, comprising

applying a volume of between 0.01  $\mu$ l and 20  $\mu$ l of a liquid sample representing the liquid analyte material, or particles isolated from a volume of a liquid sample representing the liquid analyte material, to an exposing domain from which exposing domain electromagnetic signals from the sample in the domain can pass to the exterior,

5 exposing, onto an array of active detection elements, an at least one-dimensional spatial representation of electromagnetic signals having passed from the domain, the representation being one which is detectable as an intensity by individual active detection elements, under conditions which will permit processing of the intensities  
10 detected by the array of detection elements during the exposure in such a manner that representations of electromagnetic signals from the biological particles are identified as distinct from representations of electromagnetic signals from background signals, the conditions involving such a linear enlargement that the ratio of the image of a linear dimension on the array of detection elements to the original linear dimension in  
15 the exposing domain is smaller than 10:1 and such that the individual particles the parameter or parameters of which is/are to be assessed are imaged on at the most 25 detection elements of the array of detection elements,

the sample in the domain or sample compartment being at stand still during the  
20 exposure, and in the case where at least a major part of the electromagnetic radiation emitted from the sample during exposure originates from or is caused by electromagnetic radiation supplied to the sample from a light source, then at least a major part of the radiation from the light source having a direction which is transverse to the wall of the sample compartment or a plane defined by the domain,

25 processing the intensities detected by the detection elements in such a manner that signals from the biological particles are identified as distinct from background signals,

and correlating the results of the processing to the at least one quantity parameter  
30 and/or the at least one quality parameter of the liquid analyte material.

46. A method according to claim 45, which shows any of the features claimed in any of claims 2-8, 12-13, 16-22, 24-30, 32-33, and 35.

47. A method according to claim 45 or 46, which shows any of the features claimed in any of claims 37-44.

48. A method according to claim 45 or 46, wherein the parameter to be assessed is the presence or non-presence of a particular type of particles in the liquid analyte material.

49. A method according to any of the preceding claims, wherein particles isolated from a liquid sample representing the analyte are applied to the exposing domain or arranged in the sample compartment, the particles being retained on a particle retaining means selected from means chemically binding the particles, means capable of electronically or magnetically retaining the particles, and filtering means.

50. A method according to any of the preceding claims, wherein the signal which is detected by the detecting elements originates from one or several types of molecules of types which bind to, are retained within, or interact with, the biological particles, such molecules being added to the sample or the isolated particles before or during exposure, the molecules being molecules giving rise to one or several of the following phenomena: attenuation of electromagnetic radiation, photoluminescence when illuminated with electromagnetic radiation, scatter of electromagnetic radiation, raman scatter.

51. A method according to claim 50, wherein an effective amount of one or more nucleic acid dyes and/or one or more potentiometric membrane dyes is added.

52. A method according to any of the preceding claims, wherein the duration of the exposure is in the range from 100 milliseconds to 5 seconds.

53. A method according to claim 52, wherein the duration of the exposure is in the range of 0.5 to 3 seconds.

54. A method according to claim 52 or 53, wherein the exposure is performed as a single exposure.

55. A method for compression of intensity information representing distinct objects scattered over an area, an object being represented by a variation in the intensity information

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- said information existing in the form of varying degrees of measurable intensity of a physical property distributed over a confined area divided into sub-areas, each of which sub-areas having assigned thereto an index uniquely identifying the sub-area,

10 the method comprising

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- determining the intensity of the physical property ,
  - a) defining a sub-area of interest situated in a group of sub-areas comprising of at least 2x2 sub-areas situated adjacent to each other,
  - b) evaluating in said sub-area of interest at least one directional derivative(s) of the measurable intensity in the sub-area of interest with respect to predetermined geometrical direction(s) in the plane of the confined area, the directional derivative(s) is (are) based on measurable intensities in sub-areas situated adjacent to or in proximity of the group of sub-area,
  - c) based on the evaluation of the at least one directional derivative an attribute is assigned to the value assigned to said sub-area of interest; the attribute represent an adjusted measurable intensity and/or information(s) related to a predetermined strategy for adjustment of the measurable intensity in the sub-area of interest or sub-areas situated adjacent to or in proximity to the sub-area of interest,
  - d) repeating the step a)-c) for substantially all sub-areas of the confined area.
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56. A method for assessing the number of biological particles in a sample, the method comprising:

- identifying and counting substantially all detection elements having intensities which are distinct from background signals,
- adjusting the result of the counting by a predefined scaling value,
- the scaling value being directly related to the number of detection elements representing a signal from a biological particle,
- the result of the scaling being correlated to the number of particles represented exposure.

57. A method according to claim 56, where the measured intensities of the detection elements have been adjusted prior to counting, the adjustment comprising the steps of:

- a) defining a range of a predetermined size in a co-ordinate system representing the intensity values of the detection elements, the size of the range being determined such that it is bigger than the representation of an biological particle having an average extension,
- b) choosing a first detection element, the first detection element being one of which the intensity is subject to an adjustment,
- c) positioning the range such that the detection element of which the intensity is to be adjusted is substantially in the centre of the range,
- d) adjusting the intensity of the detection element in the centre of the range based on the result of an investigation of at least one gradient describing the variation of the signal intensities inside the range and around the centre of the range by considering intensities of detection elements describing the gradient,

and repeating the step b) through c) until a predetermined number of detection elements has been adjusted a predetermined number of times.